

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The Effectiveness of Music Therapy with Aerobic exercise in Control of Positive and Negative Syndromes and Improving Sleep Quality in Patients with Schizophrenia

Protocol summary

Study aim

The aim of this study is finding the effects of music therapy, aerobic exercise and music therapy combine with aerobic exercise in control of positive and negative symptoms and improving sleep quality of Patients with Schizophrenia.

Design

Clinical trial with 3 experimental group (n=45); (music therapy (n=15); aerobic exercise (n=15); music therapy with aerobic exercise (n=15) and one control group (n=15), parallel groups, random assignment

Settings and conduct

The study will be performed in 8 educational sessions for three experimental groups at Darol shafa rehabilitation center in Ardabil without blinding

Participants/Inclusion and exclusion criteria

A diagnosis of schizophrenia by a psychiatrist based on Diagnostic and Statistical Manual of Mental Disorders (DSM-V); aged 18-65 years; changes in medication during the intervention; medical contraindication for physical activity

Intervention groups

Experimental group 1: 8 1-hour sessions of music therapy for 2 months; Experimental group 2: 8 1-hour sessions of aerobic exercise for 2 months; Experimental group 3: 8 1-hour sessions of music therapy with aerobic exercise for 2 months; control group: without training

Main outcome variables

Positive and negative symptoms ; quality of sleep

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171212037852N2**

Registration date: **2019-06-08, 1398/03/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-08, 1398/03/18**

Update count: **0**

Registration date

2019-06-08, 1398/03/18

Registrant information

Name

Mahdieh Jafari

Name of organization / entity

University of Mohaghegh Ardabili

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-06-27, 1398/04/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Music Therapy with Aerobic exercise in Control of Positive and Negative Syndromes and Improving Sleep Quality in Patients with Schizophrenia

Public title

The Effectiveness of Music Therapy with Aerobic exercise in improvement of symptoms in Patients with Schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

a diagnosis of schizophrenia by a psychiatrist based on the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) age 18–65 years

Exclusion criteria:

changes in medication during the intervention medical contraindication for physical activity

Age

From **18 years** old to **65 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The member of sample assigned in the experimental and control group by lottery.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

Daneshgah Ave.

City

Ardabil

Province

Ardabil

Postal code

5451917961

Approval date

2019-03-10, 1397/12/19

Ethics committee reference number

IR.ARUMS.REC.1397.291

Health conditions studied

1

Description of health condition studied

Schizophrenic patients

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

positive and negative symptoms

Timepoint

Before the intervention and 1 week after the intervention

Method of measurement

Positive and Negative syndrome scale

Secondary outcomes

1

Description

Quality of sleep

Timepoint

Before the intervention and 1 week after the intervention

Method of measurement

Pittsburgh Sleep Quality Index

Intervention groups

1

Description

Intervention group: Music therapy. Before performing music therapy, the pre-test will be performed. Music therapy will hold in 8 sessions for four weeks (twice a week). Each session last 60 min. This intervention comprise of passive music interventions including music listening. The music use in this study include eight light music that play with an mp3 player attach to a speaker. During the intervention, the participants should not draw or image to the music, but they will allow to talk about that after finishing the session. Patients will ask to concentrate on the music to become relaxed and lie in a bed or chair in comfortable position during the music therapy sessions. After performing music therapy, the post-test will be performed.

Category

Rehabilitation

2

Description

Intervention group: Aerobic exercise. Before performing the aerobic exercises, the pre-test will be performed. The aerobic exercise program consisted of eight exercise

sessions over the course of four weeks. Each session of the aerobic exercise involve stretching the large muscle groups as a warm-up (10 min), performing the aerobic exercise during the main phase (40 min), and stretching the center-based muscle during a cool-down stage (10 min). After performing aerobic exercises, the post-test will be perform.

Category

Rehabilitation

3

Description

Intervention group: Music therapy with aerobic exercise. In this group, after performing the pre-test the patients will be receive music therapy and aerobic exercise, according to the protocol of two other intervention groups that explained. In this method, aerobic exercise will be perform in the morning and music therapy will be perform in the evening. At the end of the interventions the post-test will be perform.

Category

Rehabilitation

4

Description

Control group: without training

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Darolshafa rehabilitation center

Full name of responsible person

Milad Bazazorde

Street address

Kosar Town, Darolshafa rehabilitation center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

↑The University of Mohaqeq Ardabili

Full name of responsible person

Ali Akbar Atadokht

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

↑The University of Mohaqeq Ardabili

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

The University of Mohaghegh Ardabili

Full name of responsible person

Milad Bazazorde

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available